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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,162	02/23/2004	Assaf Govari	BIO-5042	8493
27777	7590	09/28/2009	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			CWERN, JONATHAN	
			ART UNIT	PAPER NUMBER
			3737	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/785,162

**Applicant(s)**

GOVARI ET AL.

**Examiner**

Jonathan G. Cwern

**Art Unit**

3737

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16, 18-21, 23, 24, 35-37, 39-42, 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-21, 23, 24, 35-37, 39-42, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/15/09 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 7, the term "the robot" lacks antecedent basis, as it appears the preamble of claim 7 should have been amended to replace "Apparatus" with "A robot" as consistent with other claims. Thus, the preambles of claims 8-11 are in error as they refer to "The robot of claim 7", while the preamble of claim 7 was not amended.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16, 18-21, 23-24, 35-37, 39-42, and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green (5,808,665) in view of Webster (6,123,699) and Vesely (6,246,898).

Green discloses an apparatus and method for use with a steerable catheter (268R, 268L; col. 10, lines 47-61) with hand controllers (72R, 72L) and a deflectable distal tip. Green discloses an end-effector (170, 270R, 270L; col 2, lines 3-7) that moves in response to the hand-operated control means (col 9, lines 10-21). Green discloses use of a servomechanism that includes computer (42) that is well known in the robotic art (col 11, lines 44-47). Green discloses the control section as containing motors and linkages which operate the insertion section with five or more degrees of freedom (abstract, lines 12-14) and is also capable of pivoting with one or more degrees of freedom (abstract, lines 18-20). This would encompass the six dimensions of position and orientation information of the present invention. Green discloses pivotal movement of the distal tip in any direction, which would include rolling or jiggling, as well as axial movement of the outer section (150L2) into and out of the inner section (150L1) as well as rotation about the longitudinal axis (col 8, lines 58-66). Green does not disclose a thumb control explicitly.

Webster discloses sliding a button longitudinally in the length of a slot by means of thumb pressure within a control handle (col 8, lines 40-42).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to combine the steerable catheter assembly of Green with the thumb control of Webster for the purpose of manually manipulating the catheter tip in a desired path.

The modified invention of Green discloses the invention substantially as claimed except for the apparatus comprising a computer pointing device and a position sensor, wherein the controller is adapted to receive the position signal. However, Green does recognize that the system can employ well known mechanisms such as optical or electromagnetic position encoders (column 11, lines 25-27). As Green does not go into specific details in regards to these features, the Vesely reference is provided to further teach these features.

Vesely discloses a steerable catheter with position tracking and method for using (abstract, lines 2-6) and a computer pointing device, wherein a robotic controller receives the position signal and responds thereto (column 25, line 28-column 26, 48).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to have combined the modified steerable catheter of Green with the position tracking, computer pointing device, and robotic control of Vesely for the purpose of providing more accurate guided therapies.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16, 18-21, 23-24, 35-37, 39-42, and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plicchi et al. (US 2004/0254566) in view of Funda et al. (5,417,210) or Stevens-Wright (5,383,852).

Plicchi et al teach a robotic system remotely controlled by a user, wherein the system maneuvers and positions a flexible catheter in a body (see abstract). Plicchi et al. teach that the catheter tip is deflectable and rotatable (see) and that the catheter's position can be viewed on a monitor in real time (see fig. 1-3 and 7 and para. [0016]; [0032]; [0034]; [0035]; [0036], I. 1-3).

Plicchi et al. do not teach that the control is a thumb control or a position sensor located at the distal tip of the catheter.

Funda et al. teach a robotic system for steering and manipulating a catheter wherein the controller is a joystick (see col. 4, I. 21-30 and col. 6, I. 32-59). It would be

obvious to one of ordinary skill in the art that the joystick can be moved with a thumb in order to control the steering or maneuvering of the catheter. Funda et al. also teach a position sensor located in the distal tip of the catheter (see col. 5, l. 51-57 and col. 6, 25-60). Funda et al. also teach that the catheter may be moved in six degrees of freedom. See also col. 9, l. 59 - col. 10, l. 2 and col. 4, l. 35 - col. 5, l. 9 and col. 5, l. 51-57. Therefore, since the catheter can be manipulated in six degrees of freedom and the position information is relayed back to the user for any position that the catheter is in, it would be obvious that the system is capable of providing position information in all six degrees of freedom.

Stevens-Wright teach a steerable catheter with a thumb control (see fig. 1, ref. number 92).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a position sensor in or on the distal tip of the catheter and to provide a thumb control in the invention of Plicchi et al., in light of the teachings of Funda et al. or Stevens-Wright, in order to enhance the utility of the device.

### ***Response to Arguments***

Applicant's arguments filed 1/15/09 have been fully considered but they are not persuasive.

In regards to applicant's arguments concerning what constitutes a robot, examiner respectfully disagrees. As stated in the advisory action mailed 4/17/09, the term robot is not limited to the definition of the applicant, and is in fact much broader.

While applicant believes that a robot must "convey a sense that it has intent or agency of its own", this is merely the applicant's opinion. There are many robots for example which are remotely controlled by a human operator. In addition, the declaration appears to be merely opinion, with no factual data or evidence to support applicant's opinion. Furthermore, applicant's specification (page 13 for example) indicates that a steerable catheter capable of being manually manipulated by a user, can then employ a robotic control mechanism, which is adapted to hold and manipulate the catheter by generally mimicking the motions of a hand of a surgeon. The applicant is clearly referring to this type of setup as a "robotic control mechanism", and the examiner fails to see how this differs from the invention of Green or Plicchi.

In regards to applicant's arguments regarding six dimensions of location and orientation information, examiner respectfully disagrees. The examiner and applicant's representative discussed this definition in the interview on 5/27/09. The examiner maintains that this term is the same as six degrees of freedom, as is known in the art, and is taught by Green. Furthermore, Green indicates that the invention is not limited to an particular degrees of freedom, and manipulators employing any different degrees of freedom known in the art can be used (column 8, lines 44-50). Also, the Funda reference clearly describes using six degrees of freedom (column 6, lines 45-50).

In regards to applicant's arguments regarding the position sensors, examiner respectfully disagrees. While the examiner believes that Green shows the use of position sensors (column 11, lines 25-27), and simply does not go into specific detail



because it is so old and well known in the art, the Vesely reference is also provided to teach this feature (column 25, line 28-column 26, 48).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/  
Examiner, Art Unit 3737

/BRIAN CASLER/  
Supervisory Patent Examiner, Art  
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